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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,828	03/01/2001	Jacques Theze	201859US0PCT	7712

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/720,828	Theze et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 26, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15 and 26-57* is/are pending in the application.

4a) Of the above, claim(s) *1-4, 6-9, and 11-15* is/are withdrawn from consideration.

5) ☒ Claim(s) *5* is/are allowed.

6) ☒ Claim(s) *10 and 26-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 16-25 have been canceled in Paper No. 17, 2/26/03. Claim 10, amended claim 5 and new claims 26-57 (Paper No. 17, 2/26/03), are under consideration.

2. Receipt of applicant's arguments and amendments filed in Paper No. 17 (2/26/03) is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 17, 2/26/03:

(i) the objection to the specification for lack of an abstract and the "Brief Description of the Drawings".

4. Applicant's arguments filed in Paper No. 17 (2/26/03), have been fully considered but were persuasive in part. The issues remaining and new issues, are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

6a. Claims 26-57 are rejected under 35 U.S.C. § 112, first paragraph for lack of written description.

This rejection is maintained for reasons of record set forth at pages 3-8 of the previous Office action (Paper No. 15, 11/29/02).

Applicants argue that cancellation of claims 16-25 and the presentation of new claims 26-57 obviate the 35 U.S.C. § 112, first paragraph rejection of claims 16-25. However, contrary to applicants arguments, new claim 26 still recites "homologous." Applicants do not teach which

regions of said peptides (SEQ ID NO:2 and 4), are critical to the functions of the peptides. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a peptide that is homologous to SEQ ID NO:2 or 4 having the conservative changes as recited in claims 26, 28-31, nor does the disclosure provide criteria that explicitly enable such critical features. The amount of experimentation required for one of ordinary skill in the art to make the claimed invention, would be undue. It is this additional characterization of the disclosed polypeptide that is required in order to obtain the functional and structural data needed to permit one to produce a polypeptide which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

Furthermore, claims 26, 28-31, 38, 42, 54 are genus claims. Claim 26 recites "homologous peptide" and claim 28 recites "one or more conservative mutation" which limitations encompass peptide variants of SEQ ID NO:2 and 4. These terms encompass variants which means a peptide having one or more amino acid substitutions, deletions, insertions and/or additions made to the peptide molecule of amino acid sequence set forth in SEQ ID NO:2 or 4. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the nucleic acid molecule. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Therefore, one of skill in the art would reasonably conclude that the disclosure fails to

provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus of protein molecules.

6b. Claims 26-57 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

This rejection is maintained for reasons of record set forth at pages 8-10 of the previous Office action (Paper No. 15, 11/29/02).

Claims 26-57 encompass peptide variants of the peptides of SEQ ID NO:2 or 4, which claims are overly broad, since no guidance is provided as to which of the myriad of peptide molecules encompassed by the claims will retain the characteristics of the desired peptides. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applicants arguments that the standard is that of mutating a subject protein and testing to see if it retains the desired

biological activity (in this case, for the ability to bind hek) is a position that has been routinely dismissed by the courts, as shown by the decisions cited above.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of, for example, producing a peptide which is homologous to SEQ ID NO:2 wherein said homologous peptide is encoded by a polynucleotide having at least 75% homology to SEQ ID NO:1. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is d described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the two disclosed peptides, which are required for functional and structural integrity. It is this additional characterization of the two disclosed peptides that is required in order to obtain the functional and structural data needed to permit one to produce peptides which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement

issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that a peptide as recited in claim 38 will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably alter either of the two claimed peptides with any reasonable expectation that the resulting protein will have the desirable characteristics.

Claim rejections-35 USC § 112, second paragraph

7. Claims 10, 28-37, 38-41, 54-57 are rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 3-6 of the previous Office action (Paper No. 4, 2/11/98).

Claim 10 recites the limitation "the DNA sequence of claim 5". There is insufficient antecedent basis for this limitation in the claim.

Claim 28 improperly recites "one or more conservative mutation" rather than "one or more conservative mutations."

Claims 32 -37 recite amino acid substitutions. However, for example, there are several Glu and Gln amino acids and it is unclear which specific one or if all the Glu and Gln are to be substituted.

Claims 38-41, 54-57 improperly recite "homologous" rather than "homology".

Conclusion

Claim 5 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
April 4, 2003